Health Services
LOS ANGELES COUNTY

June 2, 2015

TO: Mayor Michael D. Antonovich
Supervisor Hilda L. Solis
Supervisor Mark Ridley-Thomas
Super visor Sheila Kuehl
Supervisor Don Knabe

FROM: Mitchell H. Katz, M.D.
Director

SUBJECT: **INCIDENT AT LONG BEACH COMPREHENSIVE HEALTH CENTER (LBCHC)**

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To ensure access to high-quality, patient-centered, cost-effective health care to Los Angeles County residents through direct services at DHS facilities and through collaboration with community and university partners.

I am sorry to tell you that we are preparing to notify 53 patients who received dental care at the Long Beach Comprehensive Health Center (LBCHC) between April 21, 2015 and May 1, 2015, that they were possibly exposed to incompletely sterilized instruments and should return to the LBCHC for testing to ensure that they did not contract HIV or hepatitis from the exposure. After review of the problem and consultation with several infection disease experts, I believe the risk of transmission of infection is exceedingly low, perhaps impossible. However, out of an abundance of caution, we will notify patients and conduct testing.

The problem was discovered during routine monitoring of the instrument sterilization process. Once the problem was detected, all dental care at LBCHC immediately stopped. The problem has since been traced back to user error (the sterilizer operator had recently made a small change in her process based on the advice of a clinician). The users have been reeducated; the process has been confirmed to be working properly; and dental care has resumed at LBCHC.

There are several reasons why we believe that the risk of transmission is exceedingly low. First, the cleaning of instruments is a multi-step process, of which sterilization is only one step. Before the instruments are sterilized; they are washed, scrubbed, and then placed in an ultrasonic cleaning bath for one hour. It is very unlikely that any virus - especially the HIV and hepatitis viruses - would survive this process. Second, the instruments were run through the sterilizer. Their packaging and the sterilizer's internal monitoring system both indicate that they reached the necessary temperature. Finally, because the surveillance monitoring happens once a week, it is entirely possible that all of the sterilization cycles between the last "negative" result and the first "positive" result were run correctly and that no pathogen could have been present.

To prevent recurrence of this unfortunate event, DHS is reviewing the instrument cleaning in all locations providing dental care, to ensure that proper procedures are followed, and that staff receive proper instruction.

Background:

The dental services performed at LBCHC are exams, cleaning, scaling, and cavity fillings. Like most dental clinics, some of the instruments used at LBCHC are re-usable. Processing for re-use entails two cleaning steps and the final sterilization. The first cleaning entails brushing and rinsing the instruments to remove any visible blood or debris (much like one does when hand washing dishes). After this cleaning, the instruments are soaked in a sonic bath with enzymatic solution for one hour for additional cleaning of non-visible contaminants. After soaking, the instruments are rinsed and put in packages to be sterilized. They are then put in a steam sterilizer that uses heat to sterilize the instruments. The sterilizing step is used to ensure elimination of bacterial, viral, and fungal pathogens that might remain on the instruments after the two cleaning steps. The sterilization cycle takes anywhere from a few minutes to over an hour, depending on the settings and what type of instruments are being sterilized. After sterilization, the instruments are kept in the packages until they are used again.

Effective sterilization is ensured with use of two monitoring indicators. The first is “chemical monitoring" that entails a small indicator strip on each package that changes color after exposure to a certain temperature. The second is weekly “biologic” testing. Biologic testing entails putting a vial with very hard to kill bacterial spores through the sterilizer. Spores are like a protective covering that makes the bacteria hard to kill. If, after 48 hours, there is no growth, then we have a second proof that the sterilization was done properly. If the vial shows that there is bacterial growth, it is an indication that sterilization was not complete.

What happened in this case:

In September of 2014, a new sterilizer machine was installed in the dental clinic at LBCHC. Between September 2014 and late April 2015, the monitoring indicators showed that the sterilization process was working properly. In late April, the technician who does the cleaning, disinfection, and sterilization made a small change to her process on the advice of a clinician because the clinician was concerned about damage to the “new” sterilizer. To avoid damage to the new equipment, the technician was encouraged not to close the door quite so tightly. (The door is held closed by a twist crank).

The April 20, 2015 biologic sample showed complete sterilization. However, the biologic sample taken on April 27, 2015 and returned on May 1, 2015, showed bacterial growth, indicating that the sterilization was not complete for that run. Upon receiving this result on May 1, 2015, LBCHC stopped all dental care and began a review. It was determined that 53 patients were exposed to reusable dental instruments between April 21 and May 1, 2015. (We went back to April 21st because April 20th was the last known “negative” biologic test).
In the ensuing week, repeat biologic tests were run and the sterilizer was examined by Harbor-UCLA Medical Center’s (Harbor’s) biomedical department in an attempt to diagnose the problem. Of eight repeat biologic samples over five days, five were negative (including one run that had two negative and one positive result). On May 11, 2015, Harbor’s biomedical department instructed the dental technician to call the manufacturer. The same day, while on the phone with the manufacturer, the dental technician noticed that steam was emanating from around the door seal of the sterilizer despite the fact that the “door closed” light was on and the sterilizer appeared to be operating normally. She had not noticed the steam before because she usually attends to other tasks while the sterilizer is running. The manufacturer’s representative pointed out that the light can come on even if the door is not tightly sealed with the crank handle

closure. This is noted in one line of the operator's manual for the sterilizer and could be seen as a design flaw. The dental technician was instructed to close the door more tightly.

Repeat biologic samples were sent May 12-14, 2015 to ensure that the problem had indeed been addressed. On May 18th, these samples were all noted to be negative and care was resumed as of May 19th.

Assessment:

DHS continues to work to determine assess factors that contributed to this problem, whether the risk exists elsewhere in the system and what should be done to prevent recurrence. At this time it appears that the following factors contributed to the problem:

- The sterilizer door is held closed by a crank-turning mechanism. Concerned about damage to the new equipment, a clinician in the dental clinic instructed the dental technician to not close the door so tightly. Based on this instruction, she changed her process and began to tighten the door a bit less than before.
- The presence of positive biologic tests coincides with the change in sterilizer door tightening by the dental technician.
- The "door closed" light will illuminate even if the sterilizer door is not tightly sealed. This is noted in the operator's manual, but was not well known by the staff.
- The sterilizer will not run through a cycle if the door is too far open to make a seal. However, it appears that it will run if the seal is made, but not tightly.
- As the dental technician eventually noticed, this means that unless observed carefully, the sterilizer may appear to be working properly even though it is not.

Based on the following factors, we believe that the risk of transmission of HIV, Hepatitis B, or Hepatitis C (the primary infections of concern) is very low:

- Chemical indicators on each sterilized bag indicate that the target temperature was reached.
- Positive and negative biologic results from the same sterilizer run may be explained by placement in the machine (front vs. back) when the door is not very tightly closed. When the sterilizer at LBCHC was run, the biologic vial was generally placed at the front of the machine, near the door, with the instruments further in.
- The hand washing and cleaning should remove most, if not all, concerning pathogens.
- The biologic is harder to kill than the pathogens we are concerned about. This means that even though the biologic result was positive, it is quite possible (or even likely) that any pathogen remaining after the cleaning would still have been killed by the sterilizer.
- Review of the medical literature and conversation with the US Centers for Disease Control indicate that problems in the cleaning and sterilization of dental instruments is common across the United States, and that transmission of infections in such events is very rare.

Actions:

In order to mitigate the effect of these events, assess whether the problem exists elsewhere in the system, and to prevent recurrence, DHS has completed or is engaging in the following actions:

- DHS will contact the 53 patients who may have been exposed to incompletely sterilized instruments. They will be informed of the possible exposure and provided with free consultation and testing.
- Re-educate staff at LBCHC regarding the correct use of the sterilizer and the known issue regarding the “closed” light. (complete)
- Review sterility monitoring process and make any appropriate changes to ensure timely information. (In process)
- Contact all other DHS facilities doing dental care to: (a) ensure that if they are using the same equipment, that they know of this issue; (b) to instruct them to review their instrument cleaning and sterilization practices, and make sure they are being done appropriately. (In process. So far, 5 other facilities that do dental care have reported that they do not use the same machine)
- Review instrument stock levels and acquire additional instruments if necessary. (In process)

If you have any questions, please let me know.

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c: Chief Executive Office
County Counsel
Executive Office, Board of Supervisors